Health Effects Institute
Science to Inform Policy

Bob O'Keefe, Vice President
Health Effects Institute

Clean Air Act Advisory Committee
Washington, DC
May 2008

The Health Effects Institute

- Over 25 years of providing impartial, high-quality science on health effects of air pollution
- From the beginning, joint and equal core funding from
  - Government (U.S. EPA)
  - Industry (Worldwide Vehicle and Engine Manufacturers)
- Expanded major partnerships with:
  - Oil, steel, paper, utilities, chemical
  - DOE, FHWA, California, USAID, WHO, EU, ADB,, other agencies and Environmental NGOs
- Over 260 studies – selected competitively from best institutions around the world

HEI Structure and Approach

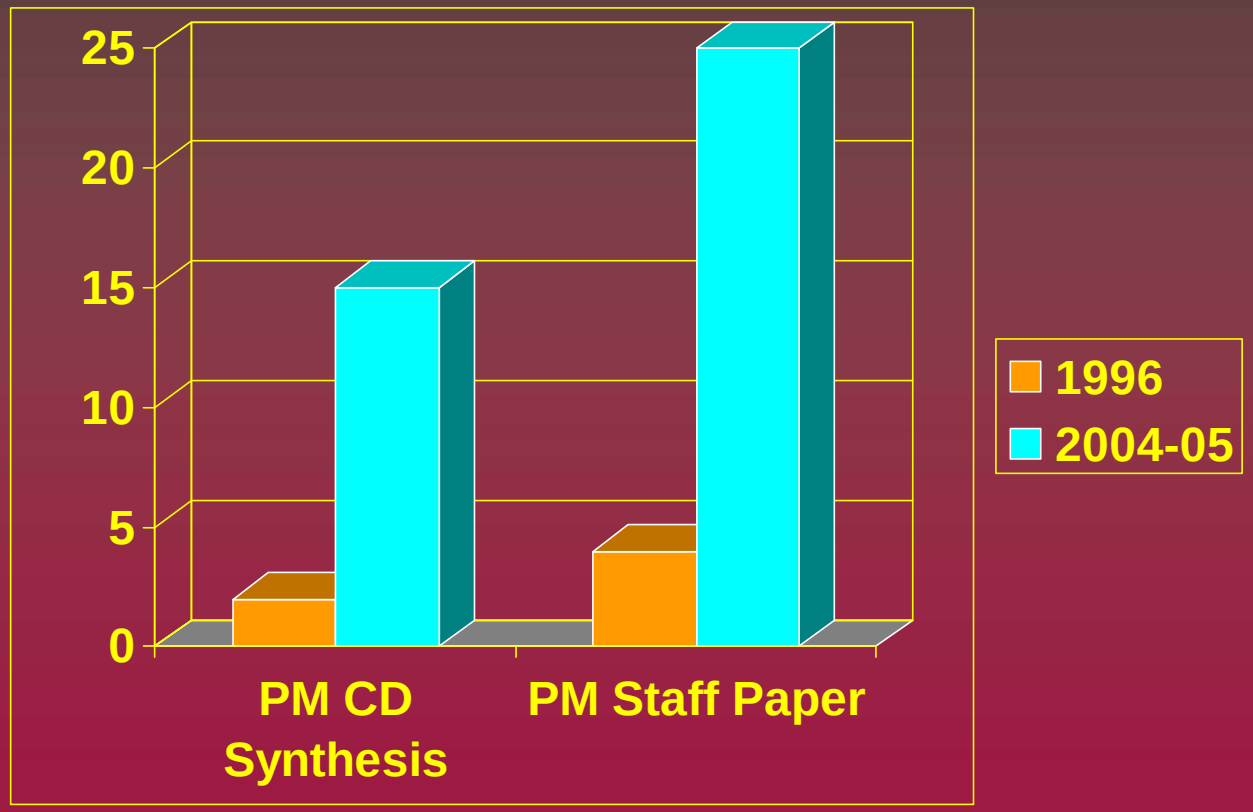
- HEI structured to maintain credibility & transparency in often controversial regulatory debates
  - Balanced government and industry funding
  - Independent Board and Expert Science Committees
    - Not affiliated with sponsors – no perceived "point of view"
    - Board agreed to by EPA Administrator and industry
    - ***Research Committee*** selects all research competitively
    - Separate ***Review Committee*** intensively peer reviews all results
  - All results and data – both positive and negative – reported
- **Does *not* take policy positions**

HEI Products

- ***Targeted Interdisciplinary Research***
  - Key regulatory questions: NAAQS, air toxics, fuels & additives, (toxicology, epidemiology, exposure etc.)
  - Studies on particulate matter, ozone, diesel, carbon monoxide, exhaust, benzene, butadiene, many others
- ***Re-Analysis***
  - e.g. Harvard Six Cities and American Cancer Society Studies on PM; 30 revised "time-series" PM studies
- ***Review & Synthesis of Existing Science***
  - Traffic, MTBE, Diesel Exhaust Epidemiology, Air Toxics,
- ***Continuous Improvement in Methods***
  - Development and application of the best methods for statistics, exposure, toxicology

Having an Impact:
HEI in the PM NAAQS

(Number of HEI Reports cited in U.S. EPA PM NAAQS Documents)



HEI Funding Studies in Many Locations

To Inform Increasingly International Environmental Decisions

★ = HEI Study

The HEI Strategic Plan 2005 – 2010

developed with broad input from sponsors, science, stakeholders

- Targeted *Priority Topics:*
  - Health effects of the air pollution mixture
    - Particulate Matter
    - Ozone and other gases
    - Air toxics
  - Emerging fuels and technologies (e.g., 2007-2010 diesel, manganese, biofuels)
  - Assessing the public health impact of air quality actions (accountability)
  - Enhanced international perspective

National Particle Toxicity Component Initiative (NPACT)

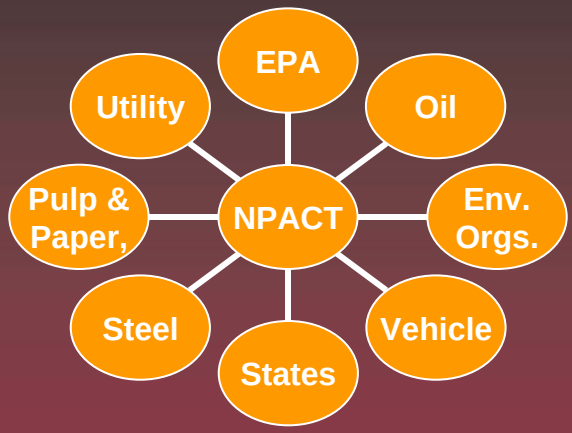
Systematic, multidisciplinary program to compare toxicity of PM components, gases, and sources.

Multi–Sector/ Government Initiative

Teams from UW,LLRRI NYU, Yale

Detailed monitoring data, and integrated tox, long and short term epi, exposure assessment

Initiated in 2007



Comprehensive 5-year Program designed to deliver near term and longer term results to inform:

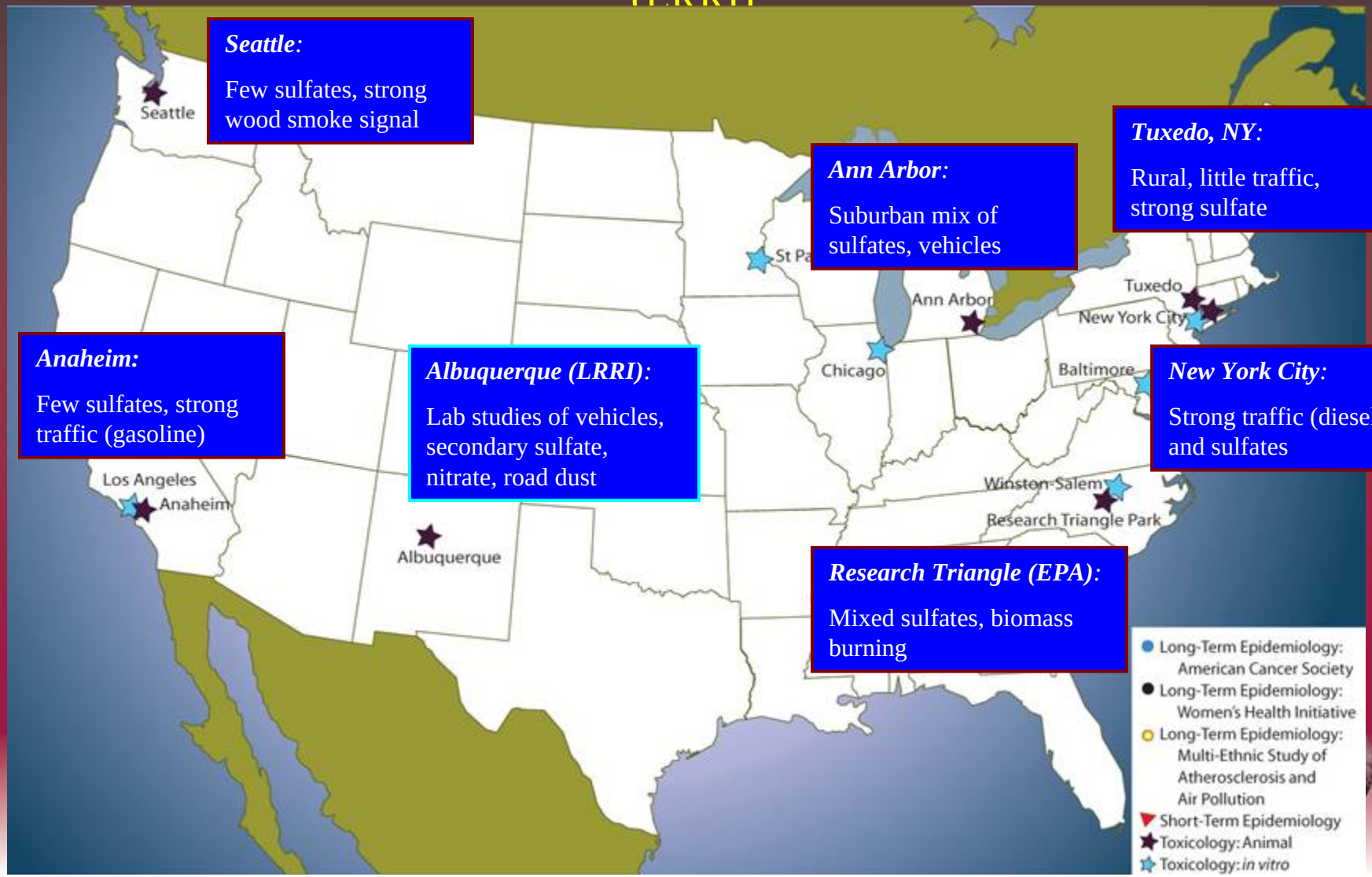
- Future PM, gaseous NAAQS decisions
- Key federal state and local decisions, (e.g. future vehicle, boiler, and utility PM rules).
- **Initial results in 2009 and 2010;**
- Comprehensive results of all studies expected in 2011 and 2012.

HEI's National Particle Component Toxicity Initiative (NPACT)

Coordinated Toxicology and Epidemiology in Over 100 Cities

Toxicology

Integrated 6-month mouse ambient studies in diverse PM settings (NYUMC) **compared with** subchronic source specific exposures for similar mouse model (LRRI)



Seattle:

Few sulfates, strong wood smoke signal

Ann Arbor:

Suburban mix of sulfates, vehicles

Tuxedo, NY:

Rural, little traffic, strong sulfate

Anaheim:

Few sulfates, strong traffic (gasoline)

Albuquerque (LRRI):

Lab studies of vehicles, secondary sulfate, nitrate, road dust

New York City:

Strong traffic (diesel) and sulfates

Research Triangle (EPA):

Mixed sulfates, biomass burning

Accountability

- Assessing the Health Impact of Environmental Regulations

-Are regulations achieving the intended public health benefits?

-Use real data (not models) to measure impact of regulation along entire chain from:

Regulatory action → emissions → air quality → exposure → human health

HEI studies:
Assess Short-term interventions

Occur over very short period of time, acute effects

Traffic reduction measures

1. London congestion charging scheme
2. Low emission zone in London

Targeting fuels & combustion

4. Cleaner wood stoves in Montana
5. Coal ban in Irish cities
6. Reducing sulfur in fuel in Hong Kong

Multiple sources

7. Reducing traffic and industrial sources in Beijing in association with 2008 Olympic Games

HEI studies:
Actions and events over the longer term

implemented over longer term, many other concurrent changes

8. Regulations requiring decreased SO_2 emissions from powers plants in the eastern United States (Title IV of the 1990 Clean Air Act Amendments)

9. Changes in eastern Germany after the reunification, such as switching from brown coal to natural gas and increased use of catalytic converters and diesel engines

Cleaner wood stoves (Montana)

PI: Curtis Noonan, University of Montana

- community intervention project by Montana DEQ & others
- change-out of 1200 uncertified wood stoves during two winters (2005 and 2006)
- assess $PM_{2.5}$ levels outdoors, in schools, and in homes before, during and after wood stove replacement

relate air quality to children's respiratory symptoms, infections, and illness-related school absences

- Do we see a decrease in pollution and health outcomes over existing baseline?

2008 Olympics (Beijing)

PI: Jim Zhang, University of Medicine and Dentistry of New Jersey

Assess effect of efforts to reduce emissions from traffic and industrial sources in period leading up to and during Olympics

- Measures (already started), targeting industry, fuels in Beijing area,
- Additional two-tiered approach during the Olympics:
  - (1) keep highly emitting vehicles off the road and restrict operation of high emitting industries (July 25 – September 17)
  - (2) restrict additional vehicles and factories during actual competition (August 8–24)

-Baseline air monitoring (before), during, after interventions

-Biomarkers in PKU medical students during same Olympic period to assess

- -blood coagulation
- -systemic inflammation

Health Impacts of Traffic

“Roadway” Effects

- Growing number of studies looking at exposures and effects at roadside
  - High levels of some pollutants
  - Substantial populations potentially affected especially in urban areas, some low SES
  - Exposure, Animal, and Epidemiology Studies
  - Crude Exposure metrics
    - Difficult to separate sources

Time Spent in Traffic and Heart Attack

HEI Study (Peters et al 2005)

-Found elevated risk of MI for those in traffic 2 hrs prior to event

- Noise, stress could also play role

The NEW ENGLAND JOURNAL of MEDICINE

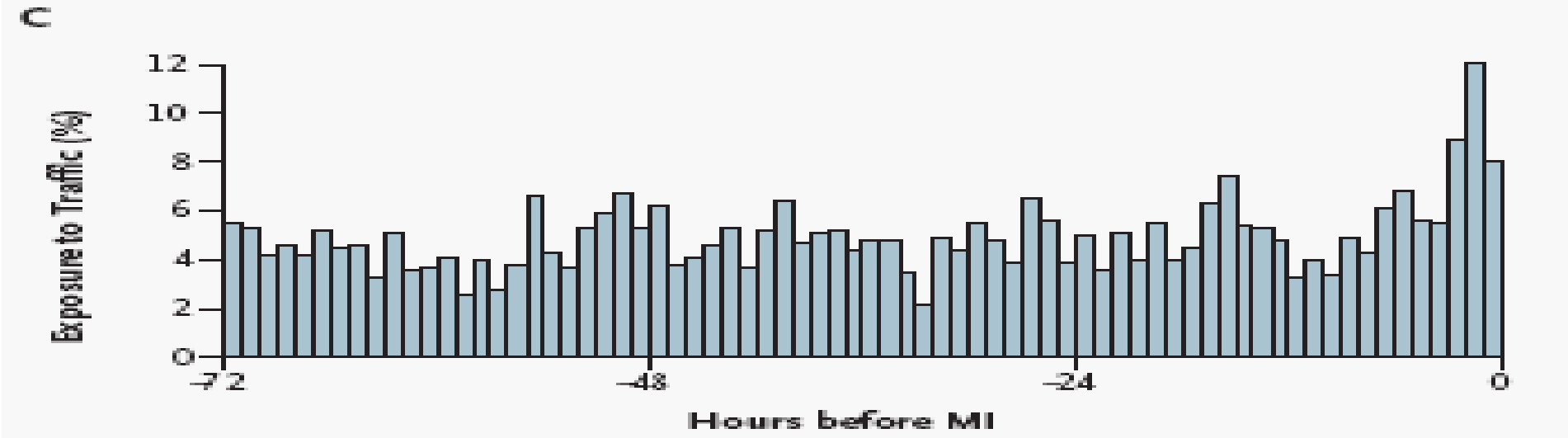


Figure 1. The Onset of 691 Nonfatal Myocardial Infarctions (MI) in Relation

Critical Review of Studies of Health Effects of Traffic- Related Air Pollution

- HEI Committee Chaired by Ira Tager, UC Berkeley
- Review of scientific literature from 1986 (start of diesel emission control) to 2007
- Initiated Spring 2007, first drafts completed
- Key areas:
  - Emissions Characterization
  - Exposure Assessment
  - Epidemiology (including statistical issues raised by epi studies)
  - Toxicology

Over 500 studies reviewed (!)

Publication expected in 2009

International

International Perspective

(support from foundations, Asian Development Bank, others)

- Modest, sustainable international program:

Apply the best science from throughout the world to inform US decisions

- Air Pollution & Health a combined European and North American Approach (APHENA), (studies of acute effects across two continents)
- Brunekreef (long term effects of exposure to traffic in NL)

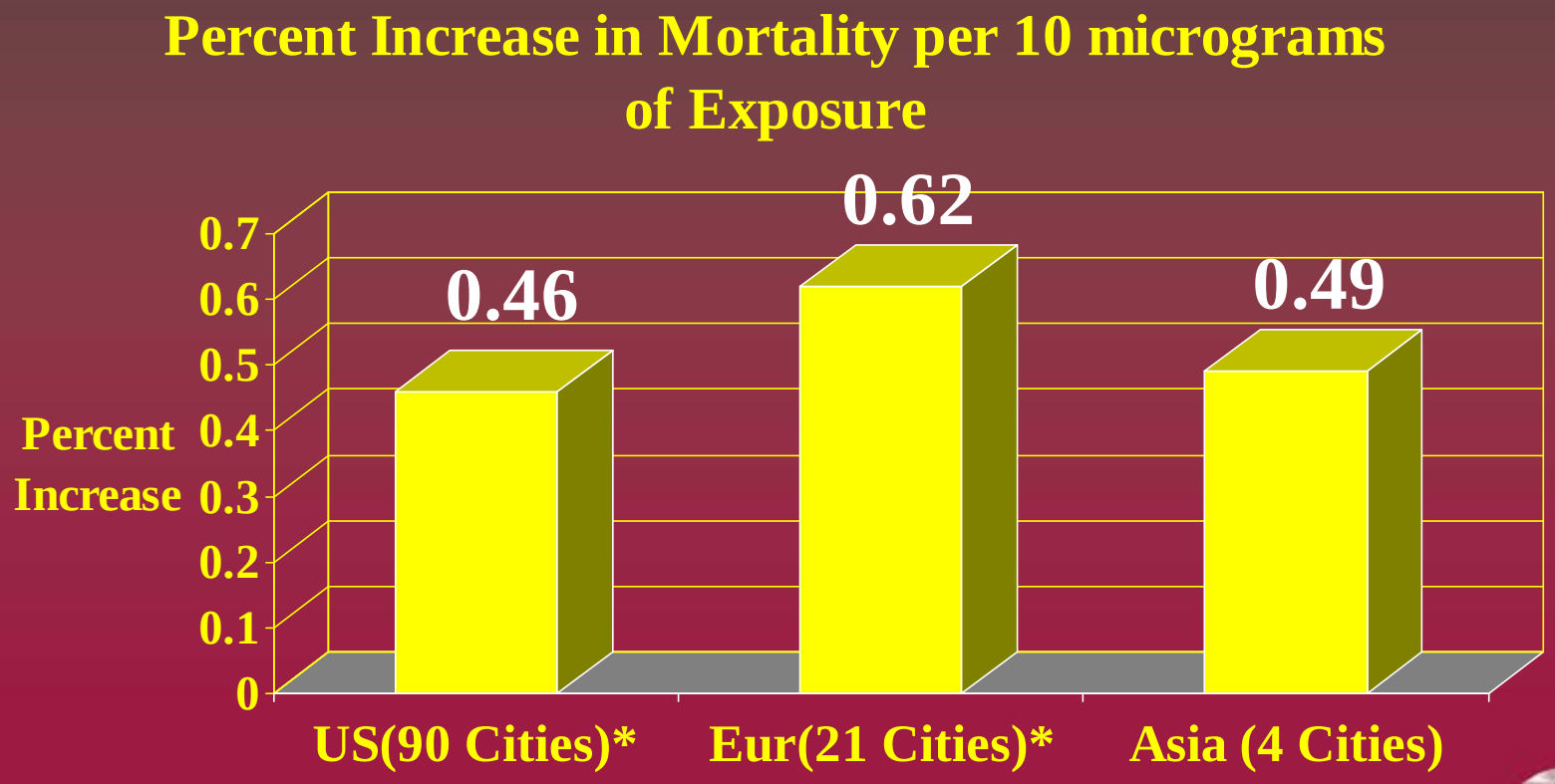
– ***Inform Air pollution and health decisions in emerging markets of Asia, Latin America. High pollution, dense urban populations, public health impacts***

- PAPA" Studies of acute effects in 7 Asian cities (China, India, Thailand)
- Air pollution poverty and health in year two in Vietnam,
- PAPA-SAN, 1st ever web database of Asian science literature updated, >450 studies
- Benchmark Review: The Health Effects of Air Pollution in Asian Cites

Regular Communication of HEI science in high level international forums

- PM Health Effects Japan EPA\industry (setting new national PM 2.5 standard)
- In China, effects of NO2 and SO2, low sulfur fuels, (as part of USEPA, industry, MEP trilateral)
- Diesel health effects in India (SIAM \ worldwide vehicle industry \government forum)

PAPA Review Initial Results: Asian Risk Estimates Similar to West



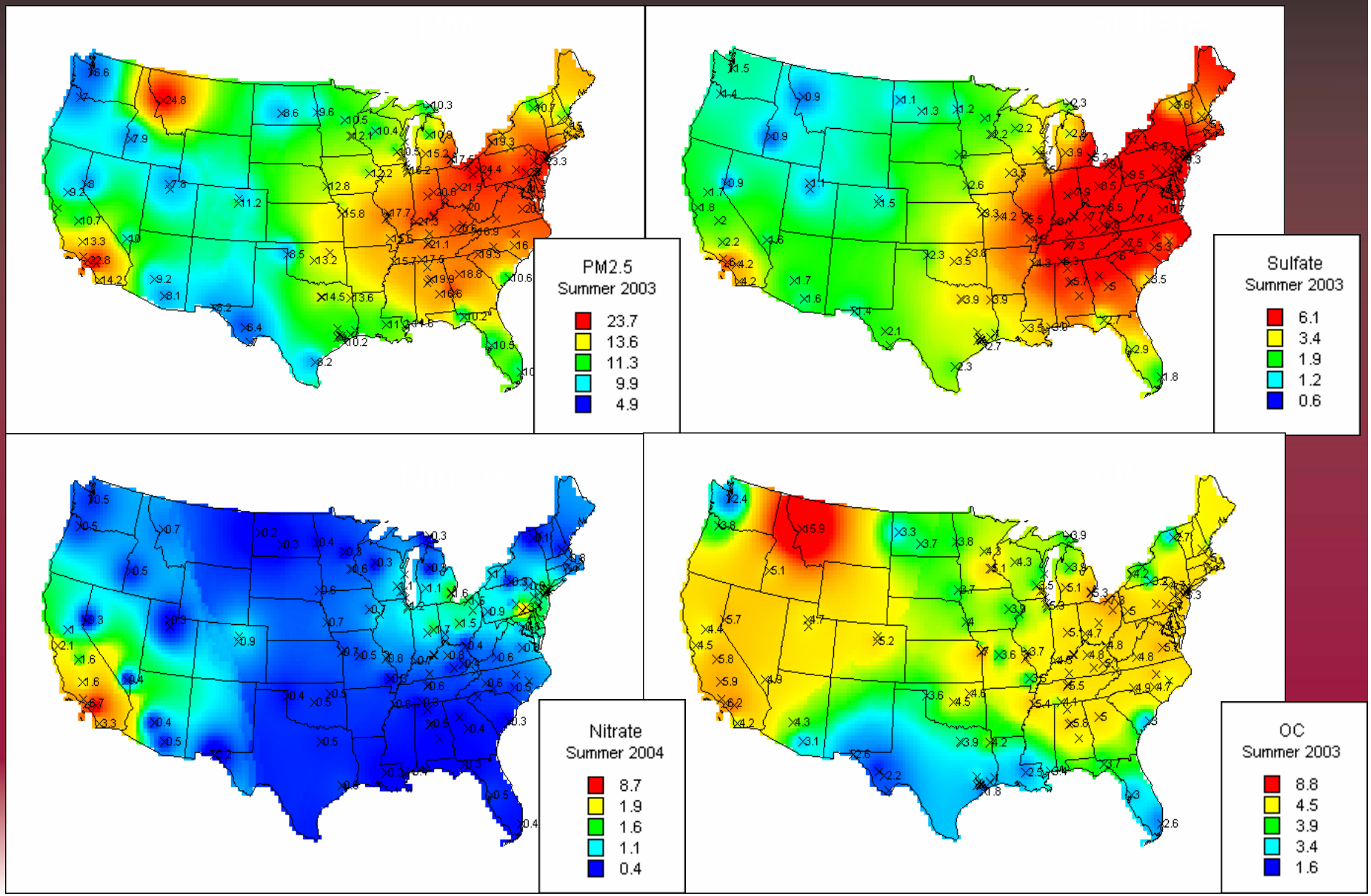
* Estimates Using Pre-GAM Results (without revision)

Summary Activities, Next Steps

- Current Studies, Reviews, New Areas:
- NPACT, other PM & Gas Studies, ACES, Air Toxics, Accountability, others
- Completing Currently Active Science Reviews
  - Traffic
  - Asia health effects, in global context
- Expected New Areas for Research, Scientific Review
  - Emerging fuels and technologies – Biofuels, NOX after treatment devices, additives, others
  - Statistical methods for Epidemiological studies
  - Air toxics hot spots
  - Accountability program summary, new research
  - Many others

Thank You

Taking Advantage of Spatial Variability: Composition of Summer $PM_{2.5}$



NEW: First Comprehensive Review of Health Effects of Air Pollution Across Asia

-Identifying health studies across Asia since 1980

-Includes levels of air pollution in Asian cities

-Asian and global standards for stationary and mobile sources

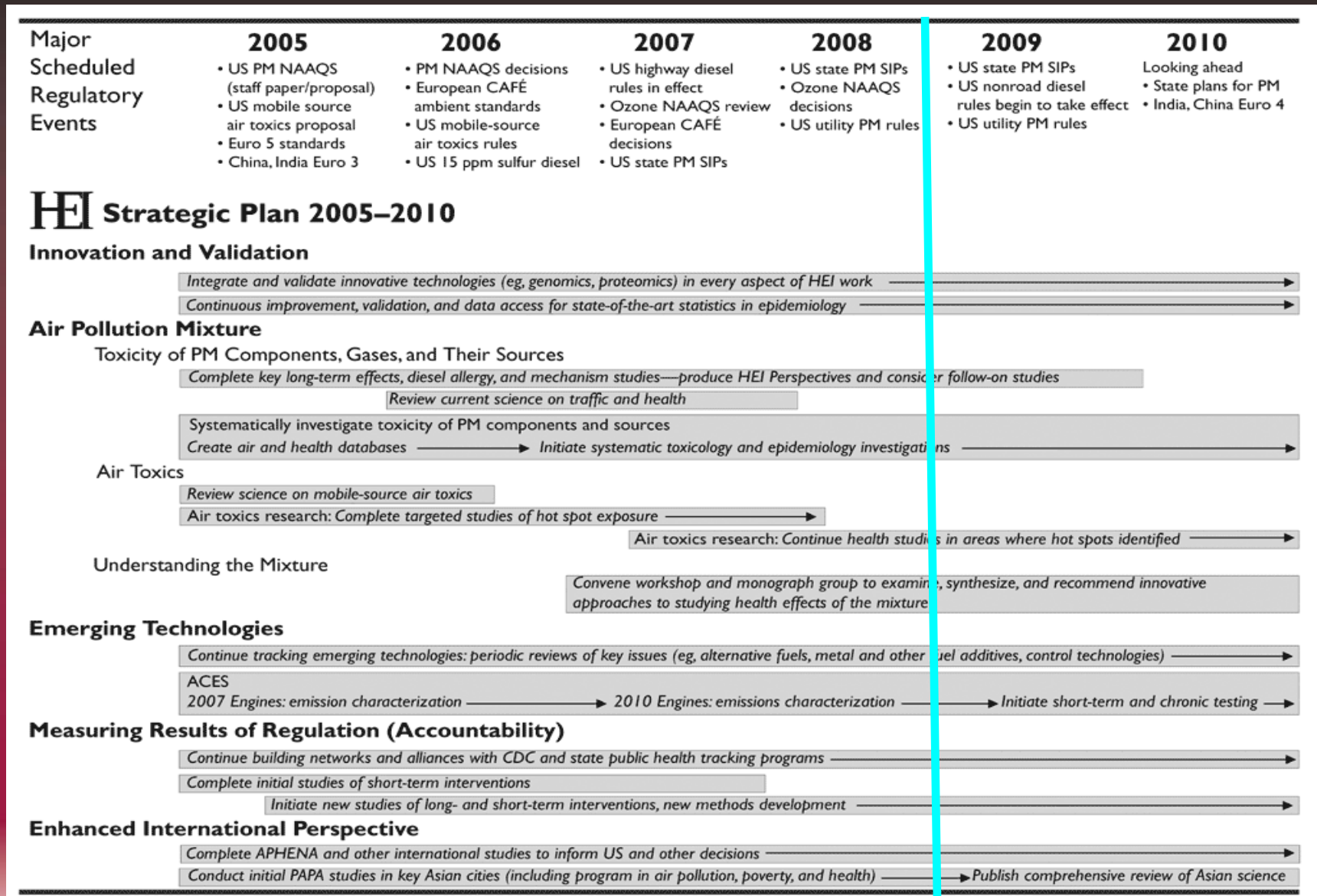
-Evaluation and new meta analysis of effects of ambient & indoor air

Including WHO Global burden of disease estimates

A new benchmark for regulators, scientists and stakeholders

Revised Final edition in late 2008

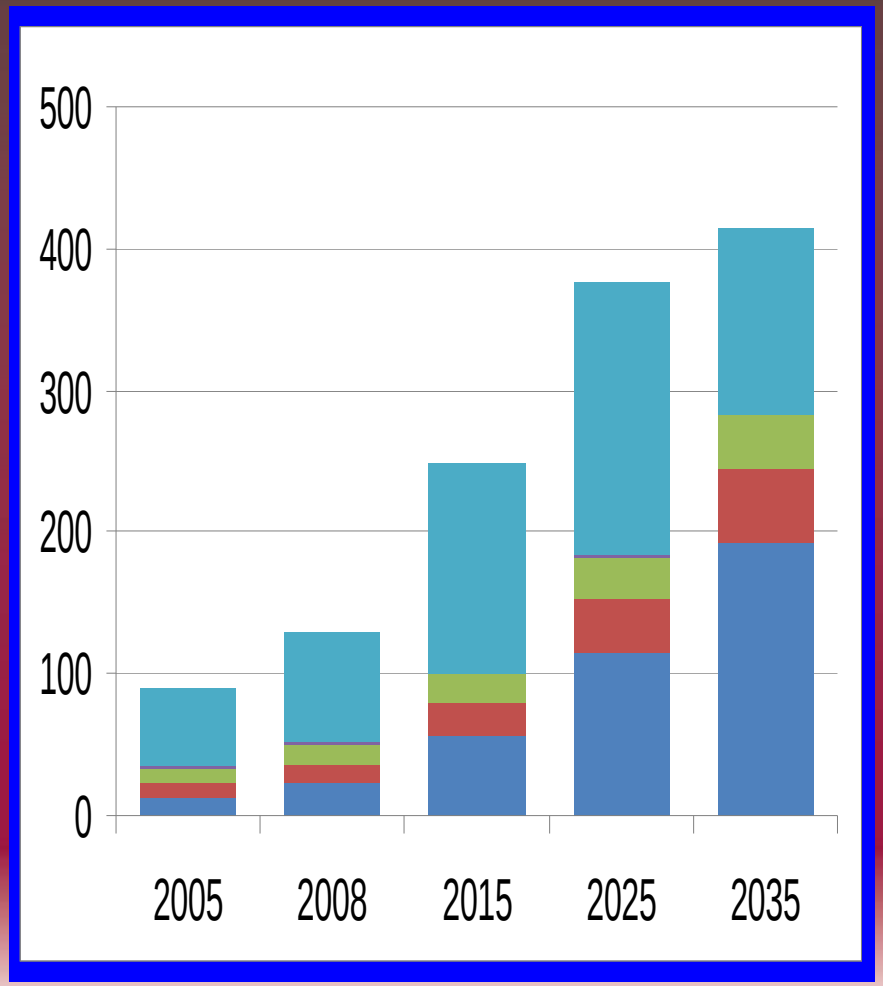
Strategic Plan: A Timeline for Action



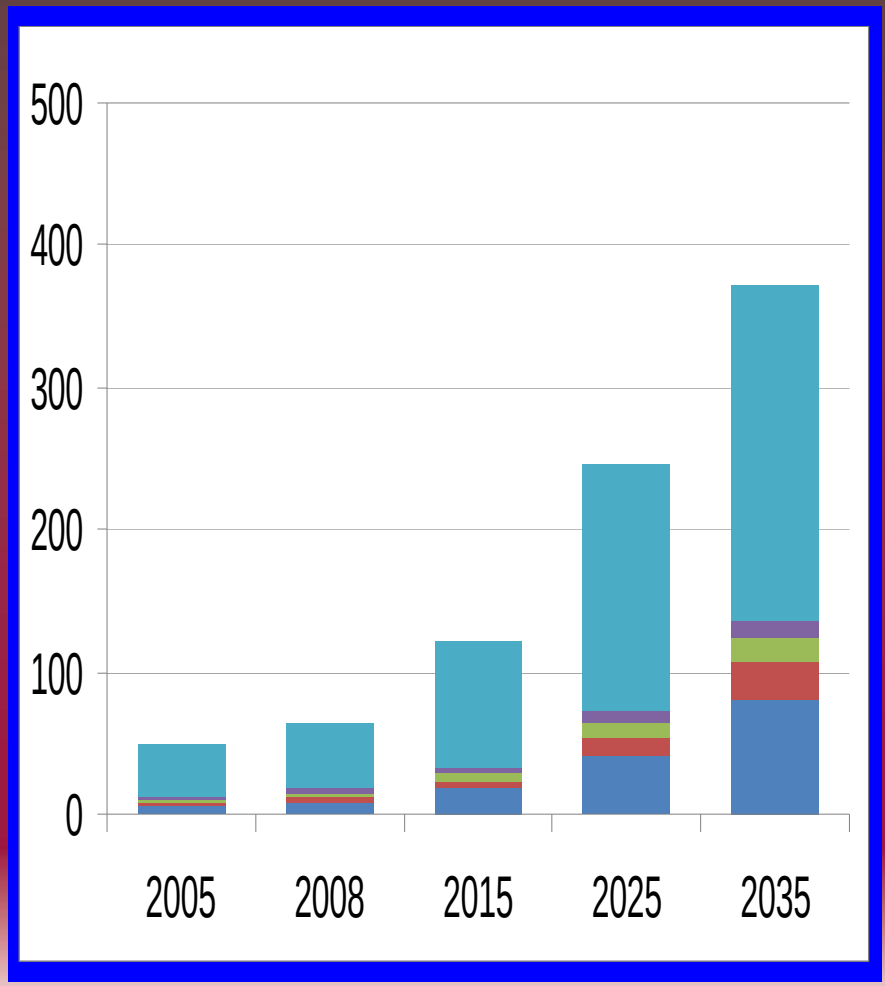
One of many growth measures: Vehicle Forecast in Asia

(in millions of vehicles)

China, P.R.



India



Concluding Thoughts

- HEI Actively engaged in producing credible science for a number of key decisions:
- Examples:
  - The rapidly moving EPA PM NAAQS process
  - Air Toxics decisions on exposure, and risk
- Many other key topics as well:
  - The gases (e.g. ozone)
  - Emerging biofuels and control technologies
  - "Accountability" measuring whether rules actually have the benefits they had been estimated to have.

Spengler Study of Air Toxics Exposure from Vehicular Emissions at a US Border Crossing

- **Objective:** Characterize impact of vehicular emissions at the Buffalo, New York Border Crossing on adjacent community.
- **Approach:**
  - Particles and gasses measured at fixed locations upwind and adjacent to the Peace Bridge Plaza where trucks and automobiles queue for customs inspections.
  - Additional fixed sites established in the neighborhoods of West Buffalo.
  - Mobile sampling systems with GPS locators will assess NO, PAH, particle mass, soot and number counts in a series of transects across the community.

Targeted Science for Decisions

- The Accelerating NAAQS Process
  - EPA Progress on a 5-year Schedule
  - HEI Studies to Inform the PM NAAQS
    - On *Long Term Effects*
    - National Particle Component Toxicity Initiative (NPACT)
- Air Toxics
  - HEI expert review of Air Toxics Exposures and Effects
  - Air Toxics "Hot Spots" –
    - *How "hot" are they?*

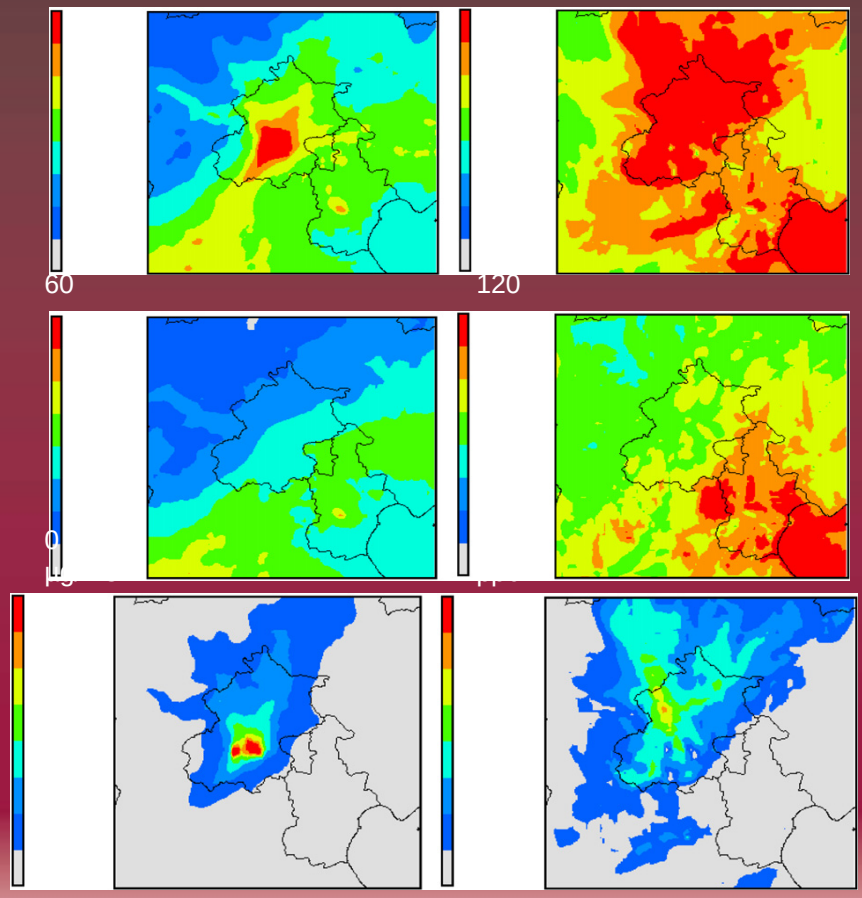
Sound Science to Sound Decisions

- India: New National Air Quality Standards
  - Largest democracy on the planet, (1.1 billion)
  - Together with China the fastest growing market for vehicles in the world
  - In process of finalizing its first set of national air quality standards for 10 (!) new pollutants and 7 additional updated standards
  - Drawing on range of science from a growing but limited base of local studies, WHO guidelines , and the literature of the developed world

Modeled Air Quality in Beijing –

David Streets et al, Atmospheric Environment 41 (2007) 480-492

CMAQ model simulations of $PM_{2.5}$ and ozone concentrations for Beijing, July 2001



All sources

Sources outside Beijing

Beijing sources alone

$PM_{2.5}$ (monthly average)

Ozone (max hourly)

HEI/CDC/EPA workshop on methodologic issues in Environmental Public Health Tracking of air pollution effects

- Build on work of CDC's EPHT program to develop indicators of air pollution-related health effects at the US state and local levels
- Bring together participants in CDC's EPHT program, US EPA's air quality programs, and US and international experts to address key methodologic issues in indicator development for public health applications
- Make recommendations to CDC regarding further development and application of indicators

EPHT workshop charge:

To develop recommendations for:

(1) approaches for using state analyses of state data to generate state and sub-state impact estimates for acute effects of air pollution;

(2) approaches for using external Concentration-Response function estimates from the scientific literature to generate local estimates for chronic and acute effects; and

(3) approaches to communicating the estimates and their limitations to stakeholders.

Key Toxics Question: How "Hot" are "Hot Spots"?

- Ambient levels of air toxics generally low
  - And most population risk estimates relatively small
- Strong citizen and scientific interest in "hot spots"
  - Concentrations of sources (traffic, industrial) near populations
- Few true tests of what is, and is not, "hot"
  - HEI completing five studies across US and in England

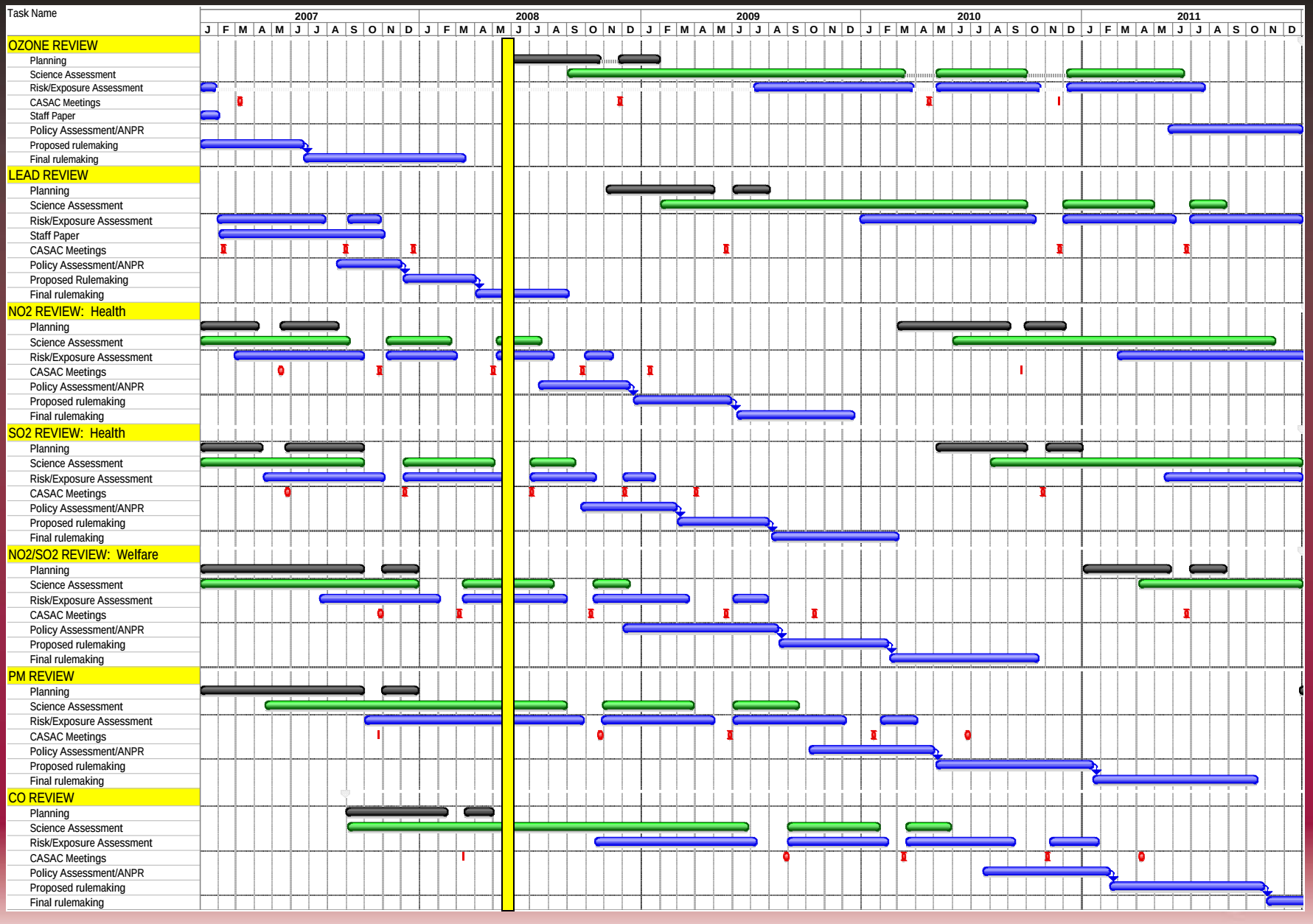
Mobile Source Air Toxics:

An HEI Critical Review of the Literature on Exposure and Health Effects

Which Toxics are likely to pose the greatest risks at ambient levels of exposure?

- What are the levels of exposure?
  - To what extent are mobile sources a significant source of exposure?
- Does it cause human health effects?
- Does it cause human health effects at ambient levels?

EPA's NAAQS Review Schedules *(as of May 2008)*



Schedule for the PM NAAQS Review

(as of February 2008 HEI Sponsor Meeting. Source: EPA)

Major Milestones		Projected Completion Date	Projected CASAC Review Date
Workshops to Discuss Key Policy-Relevant Issues		July 2007	
Integrated Review Plan	Draft Final	October 2007 February 2008	November 30, 2007
Integrated Science Assessment	First Draft Second Draft Final	September 2008 March 2009 September 2009	December 2008 * May 2009
Risk/Exposure Assessment	Draft Plan First Draft Second Draft Final	October 2008 April 2009 November 2009 March 2010	December 2008 * May 2009 January 2010
Policy Assessment/ Rulemaking	ANPR Proposed Final	June 2010 January 2011 October 2011	August 2010

*Indicates that a single CASAC meeting will address both documents

Priority Topics: Traffic and Health

- Growing number of exposure, animal, and epidemiology studies looking at exposures and effects at roadside
  - Substantial populations potentially affected
- Proximity to roadways associated with a number of effects
  - Not clear what characteristic of roadways is responsible for the association.
  - Relatively crude exposure metrics - difficult to separate sources
- Are roads a measure of
  - Exposure to PM and/or other pollutants? (gaseous pollutants, VOCs);
  - Socio-economic status?
  - Stress? Noise?
- HEI ***review*** of science on health effects of traffic.

Organization of Monograph

- Extended executive summary
  - Target technical and policy readership
- Introduction
  - Focus on 1986 (start of diesel emission control to 2020 (capture Euro 2015 standards)
- Emissions Characterization
- Exposure Assessment Methods
- Epidemiological studies
  - Statistical issues raised by epi studies
- Toxicology
- Conclusions/Research Recommentations

Priority Topic:
Assessing the Public Health Impact of Air Quality Actions (Accountability)

Studies to assess the health impact of air quality regulations

- Building on HEI Accountability Monograph, HEI has:
  - ***9 accountability studies underway***: (London low emission zone, Eastern US power plant emissions, Montana woodstove replacement, Beijing and Atlanta Olympics, fuel sulfur etc)
    - In various stages of completion and HEI review
    - Publication beginning later this year through 2010
  - ***Accountability Program Summary*** to be initiated this spring
  - ***HEI organized with CDC, EPA, states joint workshop*** on development and use of comprehensive state health tracking databases,
    - a key step in enabling studies of air quality regulations that are implemented over longer time periods (e.g. Clean Air Act)
  - Maintain receptivity to opportunistic (time sensitive) research proposals (e.g. port emission regulations)

Key Issues in the Current PM NAAQS Review

(From EPA Presentation, HEI Sponsors Meeting February 2008)

Primary Standards

- ***Indicators for fine and coarse particles*:**
  - To what extent does the newly available information support consideration of alternative indicators for fine and thoracic coarse particles?

- ***Assessment of health effects associated with long-term $PM_{2.5}$ exposures:***
  - To what extent does newly available information increase our understanding of the associations between long-term exposures to fine particles and health effects?

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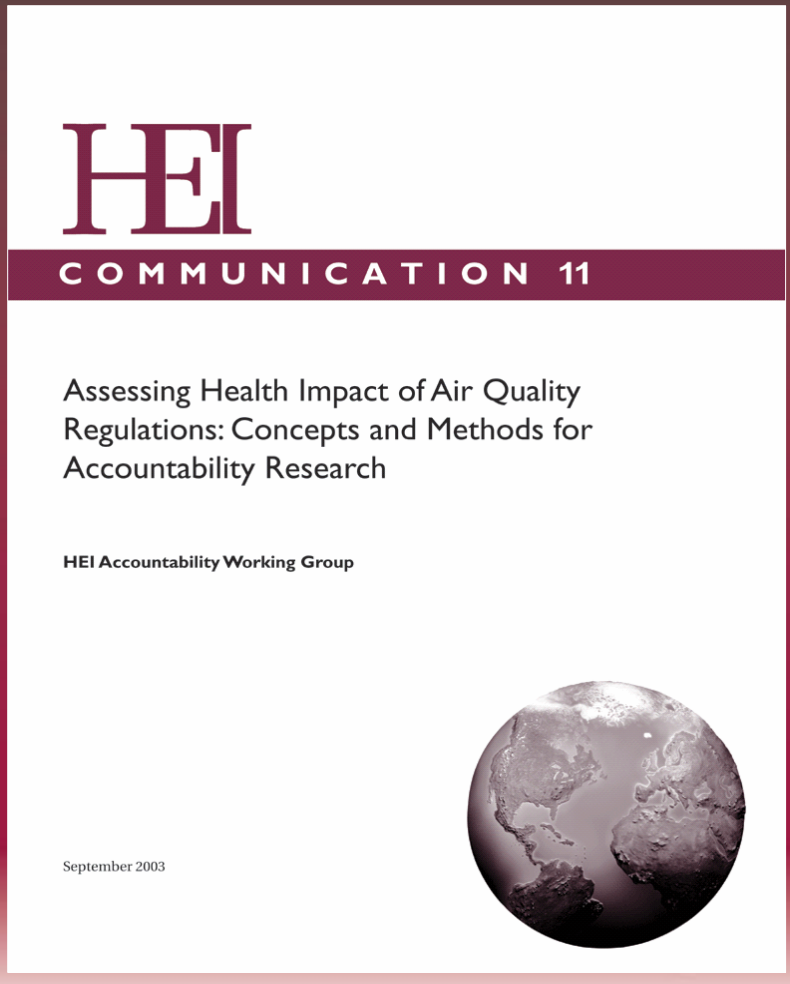
HEI Communication 11: Concepts and methods for accountability research

- Multi-authored monograph published by HEI
- Assessment of the task
- Conceptual framework for future research
- Research directions



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